



## General

### Guideline Title

Effectiveness of barcoding for reducing patient specimen and laboratory testing identification errors: a Laboratory Medicine Best Practices systematic review and meta-analysis.

### Bibliographic Source(s)

Snyder SR, Favoretto AM, Derzon JH, Christenson RH, Kahn SE, Shaw CS, Baetz RA, Mass D, Fantz CR, Raab SS, Tanasijevic MJ, Liebow EB. Effectiveness of barcoding for reducing patient specimen and laboratory testing identification errors: a Laboratory Medicine Best Practices systematic review and meta-analysis. Clin Biochem. 2012 Sep;45(13-14):988-98. [46 references] [PubMed](#)

### Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Recommendations

### Major Recommendations

Definitions for the ratings of overall strength of evidence and recommendation categories can be found at the end of the "Major Recommendations" field.

#### Conclusion and Recommendation

On the basis of a high overall strength of evidence of effectiveness, barcoding systems for specimen labeling and point-of-care test barcoding are recommended as best practices to reduce identification errors and improve the accuracy of patient specimen and laboratory testing identification in hospital settings. The high overall strength of evidence is due to sufficient evidence of practice effectiveness from individual studies demonstrating consistent and substantial reduction in patient specimen and laboratory testing-related identification error rates in hospital settings. The findings of barcoding effectiveness are based on 10 studies of specimen barcoding systems and 7 studies of point-of-care test barcoding assessing impact on identification errors. In every study barcoding is associated with a reduction in the identification error rate. The meta-analysis overall summary effect mean odds ratio favoring barcoding is 4.39 (95% confidence interval: 3.05–6.32) for barcoding systems and 5.93 (95% confidence interval: 5.28–6.67) for point-of-care test barcoding. There was limited evidence of additional benefits and potential harms associated with the use of barcoding for specimen and laboratory testing identification, and any effect of potential harms appears to be very small relative to its overall benefits. All included studies were conducted in hospital settings. No evidence was available for assessing the effectiveness and applicability of barcoding in other laboratory testing settings.

#### Definitions

## Overall Strength of Evidence Ratings

The revised definitions for these categories, modeled after the US Preventive Services Task Force (2008) are as follows:

**High:** An adequate volume of evidence is available and includes consistent evidence of substantial healthcare quality changes from studies without major limitations.

**Moderate:** Some evidence is available and includes consistent evidence of substantial healthcare quality changes from without major limitations.

**Suggestive:** Limited evidence is available and includes consistent evidence of moderate healthcare quality changes from a small number of studies without major limitations; OR the quality of some of the studies' design and/or conduct is limited.

**Insufficient:** Any estimate of an effect is very uncertain. Available evidence of effectiveness is:

- Inconsistent or weak; OR
- Consistent but with a minimal effect; OR
- Contained in an inadequate volume to determine effectiveness

## Recommendation Categories

The recommendation rating categories are consistent with the Grading of Recommendations Assessment, Development and Evaluation (GRADE) group findings (2008) and reflect the extent to which the available evidence gives one confidence that a practice will do more good than harm.

**Recommend:** The practice should be identified as a best practice for implementation in appropriate care settings, taking into account variations in implementation and/or care settings. This recommendation results from consistent and high or moderate overall evidence of effectiveness strength rating of desirable impacts.

**No recommendation for or against:** The potentially favorable impact on care outcomes and/or error reduction is not sufficient, or not sufficiently supported by evidence to indicate that it should be identified as a best practice for implementation in appropriate care settings. Additional studies may be warranted to strengthen the relevant evidence base. This recommendation results from insufficient evidence to determine effectiveness.

**Recommend against:** The practice should not be identified as a best practice for implementation because of consistent evidence of adverse effects.

## Clinical Algorithm(s)

None provided

## Scope

### Disease/Condition(s)

Any disease or condition requiring laboratory testing

### Guideline Category

Diagnosis

Evaluation

Prevention

Technology Assessment

### Clinical Specialty

Pathology

Preventive Medicine

## Intended Users

Advanced Practice Nurses

Allied Health Personnel

Clinical Laboratory Personnel

Health Care Providers

Hospitals

Nurses

Physician Assistants

Physicians

## Guideline Objective(s)

To provide a systematic review that evaluates whether barcoding practices are effective at reducing patient specimen and laboratory testing identification errors

## Target Population

All patients in healthcare settings using laboratory or point-of-care testing and their specimens requiring accurate identification for use in a healthcare context

## Interventions and Practices Considered

Barcoding practices (defined as laboratory test barcoding systems using barcoded patient identification linked to specimen labels or point-of-care testing) versus non-barcoded identification systems

## Major Outcomes Considered

Specimen and/or laboratory testing identification error rates

## Methodology

### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

# Description of Methods Used to Collect/Select the Evidence

## ASK: Review Question and Analytic Framework

The Laboratory Medicine Best Practices Initiative (LMBP) methods begin with the ASK step which frames at least one review question supported by an analytic framework and PICO elements (population, intervention/practice, comparator, outcome). The question answered by this evidence review is:

*Are barcoding practices effective at reducing patient specimen and laboratory testing identification errors?* This review question is addressed in the context of an analytic framework for the quality issue of patient specimen and laboratory testing identification errors (see Fig. 1 in original guideline document). The relevant PICO elements are:

- Population: all patients in healthcare settings using laboratory or point-of-care testing and their specimens requiring accurate identification for use in a healthcare context
- Intervention: barcoding practices defined as laboratory test barcoding systems using barcoded patient identification linked to specimen labels or point-of-care testing
- Comparison practice/intervention: non-barcoded identification systems for patients, specimens and laboratory tests
- Outcome: specimen and/or laboratory testing identification error rates are the primary and most direct outcome of interest.

## ACQUIRE: Search for Practice Effectiveness Evidence

The search for studies of barcoding practice effectiveness to reduce patient specimen and laboratory testing ID errors included a systematic search of multiple electronic databases, hand searching of bibliographies from relevant information sources and their bibliographies, provision of references by as well as consultation with experts in the field including members of the expert panel (see Appendix A in the original guideline document). Additional evidence was obtained by solicitation of unpublished quality improvement studies resulting in submissions to the LMBP. The literature search strategy and terms were developed with the assistance of a research librarian and included a systematic search in August 2011 of three electronic databases (PubMed, EMBASE and CINAHL) for English language articles from 1995 to 2012 about human subjects. The search contained the following Medical Subject Headings: automatic data processing, blood transfusion, hospitals, laboratories, methods, patient identification systems, patients, and specimen handling as well as these keywords: barcode/bar-code/bar code, labeling errors, laboratory/ies, methods/strategy(ies) reduce patient specimen handling practice/identification errors, patient identification system errors, pharmaceutical, specimen, and transfusion.

## APPRAISE: Screen and Evaluate Evidence

The ACQUIRE step search results are reviewed by an initial screening of titles and abstracts using pre-specified inclusion criteria consistent with the ASK step, followed by a full-text review of all eligible effectiveness studies, involving abstracting, standardizing and evaluating study quality using the LMBP methods. Included studies are considered to provide valid and useful information addressing the review question with barcoding effectiveness findings that include at least one ID error outcome measure. To reduce subjectivity and the potential for bias, all screening, abstraction and evaluation are conducted by at least two independent reviewers, and all reviewer discrepancies are resolved through consensus.

## Number of Source Documents

The ACQUIRE step procedures identified 1307 separate bibliographic records that were screened for eligibility to contribute evidence of the relation of barcoding with ID error outcomes. The APPRAISE step screening resulted in 1211 of these records being excluded as off-topic, and 73 being excluded for not meeting effectiveness study inclusion criteria (i.e., not a study, no barcoding practice, no ID error outcome measure) for a total of 23 full-text studies meeting the review inclusion criteria. A systematic review flow diagram in Figure 2 in the original guideline document provides a breakdown of the search results. Abstracted and standardized information as well as study quality ratings for the 23 eligible studies are provided in Appendix B in the original guideline document containing evidence summary tables preceded by a Body of Evidence table for each practice. Bibliographic reference information for these studies is provided in Appendix C in the original guideline document.

The full-text review and evaluation of the 23 eligible studies resulted in the exclusion of 6 studies due to "poor" study quality ratings which did not meet the minimum required LMBP study quality inclusion criteria (4 barcoding system studies: 3 published and 1 unpublished; 2 point-of-care test barcoding studies: 1 published and 1 unpublished). A total of 17 studies are included in this review as evidence of practice effectiveness (8 of which are unpublished submissions): 10 studies for barcoding systems (3 unpublished) and 7 studies for point-of-care test barcoding (5 unpublished). All included studies used observational before–after study designs.

# Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

## Rating Scheme for the Strength of the Evidence

### Overall Strength of Evidence Ratings

The revised definitions for these categories, modeled after the US Preventive Services Task Force (2008) are as follows:

**High:** An adequate volume of evidence is available and includes consistent evidence of substantial healthcare quality changes from studies without major limitations.

**Moderate:** Some evidence is available and includes consistent evidence of substantial healthcare quality changes from without major limitations.

**Suggestive:** Limited evidence is available and includes consistent evidence of moderate healthcare quality changes from a small number of studies without major limitations; OR the quality of some of the studies' design and/or conduct is limited.

**Insufficient:** Any estimate of an effect is very uncertain. Available evidence of effectiveness is:

- Inconsistent or weak; OR
- Consistent but with a minimal effect; OR
- Contained in an inadequate volume to determine effectiveness

## Methods Used to Analyze the Evidence

Meta-Analysis

Systematic Review with Evidence Tables

## Description of the Methods Used to Analyze the Evidence

### APPRAISE: Screen and Evaluate Evidence

To reduce subjectivity and the potential for bias, all screening, abstraction and evaluation are conducted by at least two independent reviewers, and all reviewer discrepancies are resolved through consensus. The effect size for each study was standardized using its reported data and results to calculate an odds ratio (OR) since the outcome of interest is dichotomous (i.e., correctly identified versus misidentified) and the findings for these practices are typically expressed in terms of rates or percentages. The OR compares the barcoding practice to a non-barcoding practice in terms of the relative odds of a successful outcome (i.e., the patient's specimen and/or test is correctly identified versus incorrectly identified). Each study is assigned one of three quality ratings (Good, Fair, Poor) and one of three effect size ratings (Substantial, Moderate or Minimal/none).

### ANALYZE: Evidence Review Synthesis and Results

The individual effectiveness study results from the APPRAISE step are aggregated into two practice-specific bodies of evidence (barcoding systems and point-of-care test [POCT] barcoding) and then analyzed to produce the systematic review practice effectiveness results for translation into evidence-based recommendations (Recommend, No recommendation for or against, Recommend against).

Both qualitative and quantitative analyses are used to assess effect size consistency and patterns of results across studies. Qualitative analysis is used to rate the overall strength of the body of evidence for practice effectiveness (High, Moderate, Suggestive, or Insufficient; see the "Rating Scheme for the Strength of the Evidence" field). The qualitative analysis synthesizes the individual studies to convey key study characteristics, results and evaluation findings summarized in a body of evidence table. A quantitative analysis is provided using meta-analysis of the results from similar individual studies to estimate a weighted average effect size and confidence interval using a random-effects model with the results presented in a forest plot.

## Methods Used to Formulate the Recommendations

## Description of Methods Used to Formulate the Recommendations

This evidence review followed the "A-6 Cycle" systematic review methods for evaluating quality improvement practices funded by the Centers for Disease Control and Prevention (CDC)'s Laboratory Medicine Best Practices Initiative (LMBP) (see the "Availability of Companion Documents" field). This approach is derived from previously validated methods, and designed to transparently evaluate the results of studies of practice effectiveness to support evidence-based best practice recommendations. A review team conducts the systematic review and includes a review coordinator and staff trained to apply the LMBP methods. Guidance is provided by a multi-disciplinary expert panel including at least one LMBP Workgroup member and individuals selected for their diverse perspectives as well as relevant expertise in the topic area, laboratory management, and evidence review methods. The results are translated into an evidence-based best practice recommendation by the expert panel for approval by the LMBP Workgroup.

Recommendations are formulated in accordance with the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group findings to reflect the extent to which one can be confident that following the recommendations will do more good than harm.

## Rating Scheme for the Strength of the Recommendations

### Recommendation Categories

The recommendation rating categories are consistent with the Grading of Recommendations Assessment, Development and Evaluation (GRADE) group findings (2008) and reflect the extent to which the available evidence gives one confidence that a practice will do more good than harm.

**Recommend:** The practice should be identified as a best practice for implementation in appropriate care settings, taking into account variations in implementation and/or care settings. This recommendation results from consistent and high or moderate overall evidence of effectiveness strength rating of desirable impacts.

**No recommendation for or against:** The potentially favorable impact on care outcomes and/or error reduction is not sufficient, or not sufficiently supported by evidence to indicate that it should be identified as a best practice for implementation in appropriate care settings. Additional studies may be warranted to strengthen the relevant evidence base. This recommendation results from insufficient evidence to determine effectiveness.

**Recommend against:** The practice should not be identified as a best practice for implementation because of consistent evidence of adverse effects.

## Cost Analysis

### Economic Evaluation

No patient specimen barcoding practice economic evaluations (cost, cost-effectiveness, or cost-benefit analyses) were found in the search results. Completing a resource-related inventory for barcoding practices is beyond the scope of this study but it should include the costs associated with implementing and sustaining the practice (e.g., hardware, software, equipment, supplies and labor requirements as well as resources associated with training, testing, monitoring, and maintenance) and all downstream costs and savings that occur because the intervention was performed.

## Method of Guideline Validation

Not stated

## Description of Method of Guideline Validation

Not applicable

## Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for the recommendation (see the "Major Recommendations" field).

## Benefits/Harms of Implementing the Guideline Recommendations

### Potential Benefits

The studies reviewed report beneficial outcomes associated with barcoding including an observed reduction in misidentified patients, unnecessary phlebotomy, labor time savings and reduced workflow process time in surgical pathology. Implementing barcoding has been credited with improving identification of those responsible for making ID errors, thus enabling targeted measures to improve performance. Cost savings noted from fewer ID errors associated with barcoding include reductions in specimen recollections, labor to investigate and correct ID errors, length of patient stays and legal issues. Additional benefits to patients from fewer ID errors include avoiding unnecessary discomfort, inconvenience, and treatment delays from recollecting and retesting specimens.

### Potential Harms

Barcoding technology is not error free. ID errors associated with barcoding practices include those created by the patient identification barcodes themselves. Barcode scanners may misread patient identification barcodes due to incompatibility between the barcode print area size or symbology on patient ID bands or specimen labels with scanner settings. In one study a small number of scanner misreads occurred due to the narrow wrist band curvature of pediatric patients. Other sources of barcoding ID errors included labels being unreadable by a scanner due to label print quality problems, which may indicate a need for label printer maintenance, and degradation of the barcode on the patient ID band from being worn or written on. Studies and articles have also reported scanner failure attributable to low batteries. Even when the scanner works properly, incorrect information such as the wrong patient's barcode, incorrect barcode information from a patient's ID band, or non-patient identification barcodes (e.g., medication) can cause ID errors. A specific type of ID error is from scanning incorrect barcode information from a patient ID band with a barcode related to a previous hospitalization or a hospital transfer. Such an episode could include more than one armband and/or multiple patient accounts. Although many potential sources of ID errors associated with barcoding have been identified, these errors appear relatively rare, generally preventable, and likely have only a negligible impact on ID error rates.

## Qualifying Statements

### Qualifying Statements

The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention/the Agency for Toxic Substances and Disease Registry (CDC/ATSDR).

#### Limitations

The Laboratory Medicine Best Practices Initiative (LMBP) systematic review methods are consistent with practice standards for systematic reviews, but all such methods are imperfect and include subjective assessments at multiple points that may produce bias. Like most systematic reviews, this one may be subject to publication bias, although this review includes unpublished studies which may mitigate that bias. The restriction to English language studies to satisfy the requirement of multiple reviewers for each study may also introduce bias if barcoding practices differ substantially in international settings. Quality improvement efforts typically differ from research, and are commonly observational studies that rely on natural experiments in realistic practice settings. The major drawback of these uncontrolled designs is that it is not possible to know if measured or unmeasured factors affect the outcomes of interest. Regardless of study design, by gathering evidence from multiple clinical and organizational settings, systematic reviews provide more useful assessments of the totality of evidence for a given quality improvement practice than individual studies.

Barcoding and other technology or practice changes may be easier to measure than individual step process changes that may contribute to observed results. Also, these processes are rarely uniform, and are clearly very different for clinical versus surgical pathology specimens, and for point-of-care testing. While these factors may moderate study findings and the observed heterogeneity suggests that they are not insignificant, it can

be observed that all studies reported support for barcoding.

Some studies comprising the barcoding body of evidence involved less than full implementation for all or a portion of the post-implementation period which would have an expected tendency to understate the impact of barcoding on the reduction in ID error rates. In particular, some studies indicated barcoding "scan rates" of substantially less than 100% during the post-implementation period such that the effect of a non-barcoding practice (i.e., manual entry of patient identification information) is reflected in a portion of the post-implementation data. This was noted when provided, however as it was not always clearly or consistently reported it could not be used to adjust effect size estimates. As studies were done within a single institution, there may be many site-specific differences that impact their study results. Many studies were missing information including actual study sample sizes, dates for relevant time periods, and practice implementation and setting characteristics. Another perceived limitation is the inclusion of unpublished studies.

Designing and publishing controlled studies are typically not among the primary objectives of individuals collecting and analyzing quality improvement data relevant to laboratory medicine. In the barcoding body of evidence, both the published and unpublished studies had similar limitations. The LMBP experience to date in reviewing and rating study quality for both published and unpublished studies indicates that peer-reviewed journals do *not* provide assurance of high study quality.

## Implementation of the Guideline

### Description of Implementation Strategy

#### Feasibility of Implementation

The evidence reviewed clearly demonstrates the feasibility of adopting barcoding practices in a variety of hospital settings. Nevertheless, each environment is distinctive and implementation requires adequate process development and modification, training, education and testing to achieve full effectiveness. Barcoding process design issues appear more complex for surgical pathology which typically involves more workflow process steps than patient specimens for routine laboratory or point-of-care testing. Many studies on surgical pathology describe the approach used for barcoding-related process changes in detail, along with the accompanying challenges and solutions. Key implementation components for making barcoding technology work as intended include adequate training and education, well-designed patient ID bands, and adequate supplies and equipment maintained in good working order (e.g., label printers, computers, batteries, wireless networks). Shortages and performance issues were noted as problems frustrating staff that can result in using error-prone work around processes. Support and involvement from all relevant departments and leaders including nursing, laboratory and information systems, were identified as critical success factors since no department typically has full ownership of implementing and using barcoding technology.

### Implementation Tools

#### Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

## Institute of Medicine (IOM) National Healthcare Quality Report Categories

### IOM Care Need

#### Staying Healthy

### IOM Domain

#### Effectiveness

#### Patient-centeredness



# Identifying Information and Availability

## Bibliographic Source(s)

Snyder SR, Favoretto AM, Derzon JH, Christenson RH, Kahn SE, Shaw CS, Baetz RA, Mass D, Fantz CR, Raab SS, Tanasijevic MJ, Liebow EB. Effectiveness of barcoding for reducing patient specimen and laboratory testing identification errors: a Laboratory Medicine Best Practices systematic review and meta-analysis. Clin Biochem. 2012 Sep;45(13-14):988-98. [46 references] [PubMed](#)

## Adaptation

Not applicable: The guideline was not adapted from another source.

## Date Released

2012 Sep

## Guideline Developer(s)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

Laboratory Medicine Best Practices - Independent Expert Panel

## Source(s) of Funding

Centers for Disease Control and Prevention (CDC) funding for the Laboratory Medicine Best Practices Initiative to Battelle Centers for Public Health Research and Evaluation under contract W911NF-07-D-0001/DO 0191/TCN 07235.

## Guideline Committee

Laboratory Medicine Best Practices (LMBP) Workgroup

LMBP Patient Specimen Identification Expert Panel

## Composition of Group That Authored the Guideline

*Authors:* Susan R. Snyder, Battelle Centers for Public Health Research and Evaluation, USA; Alessandra M. Favoretto, Battelle Centers for Public Health Research and Evaluation, USA; James H. Derzon, Battelle Centers for Public Health Research and Evaluation, USA; Robert H. Christenson, University of Maryland, USA; Stephen E. Kahn, Loyola University Health System, USA; Colleen S. Shaw, Centers for Disease Control and Prevention, USA; Rich Ann Baetz, Battelle Centers for Public Health Research and Evaluation, USA; Diana Mass, Associated Laboratory Consultants, USA; Corinne R. Fantz, Emory University School of Medicine, USA; Stephen S. Raab, University of Washington School of Medicine, USA; Milenko J. Tanasijevic, Brigham and Women's Hospital, Harvard Medical School, USA; Edward B. Liebow, Battelle Centers for Public Health Research and Evaluation, USA

*Expert Panel Members:* Corinne Fantz, PhD (Emory University School of Medicine); Denise Geiger, PhD (John T. Mather Hospital); David Hopkins, MD, MPH (Centers for Disease Control and Prevention); Julie Gayken, MT(ASCP)\* (Regions Hospital); Steven Kahn, PhD (Loyola Medical Center of Chicago); James Nichols, PhD\* (Bay State, Tufts University); Stephen Raab, MD, PhD\* (University of Washington); Ronald Schiffman, MD, MPH (Tucson Veterans Administration Health Center); Milenko Tanasijevic, MD, MBA\* (Harvard Medical School, Brigham and

Women's Hospital, Dana Farber Cancer Institute); Paul Valenstein, MD, FCAP (St. Joseph Mercy Hospital)

\*LMBP Workgroup member

*LMBP Workgroup, 2008–2011:* Raj Behal, MD, MPH (Rush University Medical Center); Robert H. Christenson, PhD, DABCC, FACB (University of Maryland Medical Center); John Fontanesi, PhD (University of California, San Diego); Julie Gayken, MT (ASCP) (Regions Hospital); Cyril (Kim) Hetsko, MD, FACP (University of Wisconsin-Madison, Chief Medical Officer, COLA and Trustee, American Medical Association); Lee H. Hilborne, MD, MPH (UCLA David Geffen School of Medicine, President, American Society for Clinical Pathology, RAND, Quest Diagnostics); James H. Nichols, PhD (Baystate Medical Center); Mary Nix, MS, MT(ASCP)SBB (Agency for Healthcare Research and Quality); Stephen S. Raab, MD (University of Colorado Denver School of Medicine); Milenko Tanasijevic, MD, MBA (Brigham and Women's Hospital, Dana Farber Cancer Institute, Harvard Medical School); Ann M. Vannier, MD (Kaiser Permanente Southern California Regional Reference Laboratories); Ann Watt, MBA, RHIA (The Joint Commission)

*Ex-officio Members:* Sousan S. Altaie, PhD (Food and Drug Administration); James Cometa (Centers for Medicaid and Medicare Services)

## Financial Disclosures/Conflicts of Interest

Members of the Laboratory Medicine Best Practices (LMBP™) systematic review expert panels and Workgroup are asked to provide information about financial, professional or other associations that may represent or appear to be a potential conflict related to the conduct of the LMBP™ systematic evidence reviews. The Centers for Disease Control and Prevention (CDC) LMBP™ staff reviews the conflict of interest disclosures. If a conflict arises in connection with an LMBP™ systematic review or publication, the appropriate disclosure is provided.

## Guideline Status

This is the current release of the guideline.

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Electronic copies: Available from the [PubMed Central \(PMC\) Web site](#) .

## Availability of Companion Documents

The following are available:

- Laboratory Medicine Best Practices (LMBP). Effective practices for reducing patient specimen and laboratory testing identification errors in diverse hospital settings. Atlanta (GA): Centers for Disease Control and Prevention (CDC); 2012 Feb. 3 p. Electronic copies: Available from the [Centers for Disease Control and Prevention \(CDC\) Web site](#) .
- Christenson RH, Snyder SR, Shaw CS, Derzon JH, Black RS, Mass D, Epner P, Favoretto AM, Liebow EB. Laboratory Medicine Best Practices: systematic evidence review and evaluation methods for quality improvement. Clin Chem 2011;57:816-25. Electronic copies: Available from the [Clinical Chemistry Web site](#) .
- Snyder S, Liebow E, Shaw C, Black R, Christenson R, Derzon J, Epner R, Favoretto A, John L, Mass D, Patta A, Rose S, Washington M. Laboratory Medicine Best Practices: developing systematic evidence review and evaluation methods for quality improvement phase 3 final technical report. Atlanta (GA): Centers for Disease Control and Prevention (CDC); 2010 May 27. 159 p. Electronic copies: Available from the [CDC Web site](#) .

## Patient Resources

None provided

## NGC Status

This NGC summary was completed by ECRI Institute on May 28, 2015. The information was verified by the guideline developer on August 13, 2015.

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